

REMARKS

In response to the Examiner' objection under 35 USC § 132 to the language added in the last amendment, applicant is deleting the language to the effect that the thermo-responsive material is hardness memory only. While applicant is using the hardness memory of the material, the Examiner is correct that the language that was sought to be added is not set forth in the specification as filed. Accordingly, applicant has revised the language in the claims so as not to include "new matter".

As stated in the specification, applicant uses a hardness memory material, such as the material sold under the trademark REMEMOMER and modifies its softness with polyurethane. Then applicant adds a radio-opaque material such as barium sulfate, bismuth sub-carbonate or a metal powder to the thermo-responsive material so that the short soft catheter tip made with this material can be easily moved in a blood vessel and can be easily located in a blood vessel. This is important, since the observance of a bend in the soft tip seen by reason of the radio-opaqueness of the catheter tip, will indicate to the medical personnel that an obstruction has been encountered.

Heretofore, catheter tips with radio-opaque material have been used to find out where the tip is. However, soft tips have not been used because of the difficulty in introducing them.

Now, applicant's tip allows for ease of introduction, subsequent ease of passage through blood vessels, viewing of the tip and the ability to see bending of the tip when an obstruction is encountered.

No catheter tips heretofore have provided these advantages or features prior to applicants catheter tip.

Nor have prior art catheters provided a hard-soft jacket on the catheter together

with a radio-opaque tip as called for in amended claim 21.

The Examiner's rejection of claims 11-22 under 35 U.S.C. § 112 for failing to comply with the enablement requirement as this rejection may be attempted to be applied to amended claims 11-22, is respectfully traversed.

In support of this traverse, applicant has revised the language in the claims to remove the objected to language.

The Examiner's rejection of claim 19 under 35 U.S.C. Section 102(b) for being anticipated by the Tovey US Patent No. 5,445,140, as this rejection may be attempted to be applied to amended claim 19, is respectfully traversed.

In support of this traverse, it is important to note that applicants are not claiming a shape or geometry memory tip. Applicants are only claiming a tip, which has a temperature responsive hardness memory, where the softness of the tip is modified with polyurethane and a tip which has a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder. In other words, applicants distal tip at the end of a distal tip portion of a catheter assembly, does not change its shape upon a change of temperature. Only the hardness/softness or durometer of the distal tip changes when the temperature of the distal tip passes through a critical temperature. In this respect, the distal tip will be harder at temperatures below a critical temperature and softer at a temperature above the critical temperature.

Also, applicant's hard/soft tip also has a radiopaque material therein so it can easily be seen in a blood vessel and the bending of the tip when an obstruction is encountered can also be seen.

Applicants submit that as so amended, claim 19 is not anticipated by the Tovey patent cited; and for that matter, not anticipated or rendered obvious by the Tovey patent, the Bley et al., US Patent No. 5, 762,630, or the Schroepfel, US Patent

No. 6,024,764.

The Examiner's rejection of claims 11, 12, 15 and 16 under 35 U.S.C. Section 103(a) for being unpatentable over Tovey in view of the Bley et al, US patent number 5, 762,630, and the Schroepel, US patent number 6,024,764, as these rejections may be attempted to be applied to the amended claims, is respectfully traversed.

In support of this traverse, it is to be noted that claim 11 has been amended to call for a distal portion, which is made of a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder compounded with a plastic thermoresponsive material that is modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip resulting in a temperature responsive hardness memory tip. Furthermore, claim 11 calls for the tubular body to be coated with a jacket made of the same plastic thermoresponsive material.

Applicants submit that such a catheter assembly is not at all suggested or disclosed by the references cited.

Again, while Tovey calls for an articulation providing hinge, which is harder at ambient temperature and which is tractable above a predetermined ambient temperature, Tovey does not disclose a distal tip of a distal tip portion, which is made of thermoresponsive hardness memory material modified with polyurethane and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder.

Nor does Tovey teach a distal tip, which changes form hard to soft when the tip is at a temperature above a predetermined temperature.

Rather, Tovey teaches a shape memory tip.

Furthermore, Tovey does not teach a temperature responsive hardness

memory outer jacket on a tubular body.

Looking now at the Bley et al. patent, it is noted that this patent is directed to a stylet, which is made of a hardness memory material and can also include a shape memory material, which memory materials are thermoresponsive.

Note that while Bley et al. teaches that the catheter 111 can be made of a number of different materials, including a thermally softening material, Bley et al. does not teach a catheter tip made of a temperature responsive hardness memory material modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder.

Nor does Bley et al. teach coating a tubular body with a thermoresponsive hardness memory material jacket as taught by applicant and as called for in amended claim 11.

Again, it cannot be emphasized enough that Bley et al. is only directed to a stylet made of thermoresponsive hardness memory material.

Accordingly, Bley et al., by teaching a stylet made of thermoresponsive hardness memory material does not teach or suggest a distal portion of a catheter having a distal tip, which is made of thermoresponsive hardness memory material modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder.

The Examiner has cited the Schroepel et al. patent for its teachings of a shaped memory outer jacket. Again, applicants do not provide or have a shape memory material for an outer jacket or used as an outer jacket. While Schroepel et al. discusses the fact that shape memory material often softens as its

temperature is raised, Schroepfel et al. does not teach providing a soft rubbery jacket to a catheter. Schroepfel et al. only teach a shape memory metal (Nitinol) or plastic sleeve.

The Examiner's rejection under 35 U.S.C. 103(a) of claim 14 for being unpatentable over the Tovey in view of the Bley et al. patent, as this rejection may be attempted to be applied to the amended Claims, is respectfully traversed.

First of all, in support of this traverse, applicants repeat and incorporates herein by reference the remarks made above with respect to claim 11 and claim 19 in Amendment A.

In particular, claim 14 now calls for a distal portion having a distal tip, which has a temperature responsive hardness memory tip modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder.

This claim further adds the feature that the distal portion of the tubular body is tapered and that the distal tip is welded or molded to the tapered distal portion.

The Examiner has cited the Griep, US patent number 5,163,431 in combination with Tovey and Bley et al. against claim 13.

In support of the traverse of the rejection of claim 13, applicants submit that the combination of the temperature responsive hardness memory tip combined with the other features, namely the tapered portion and the molding and welding on of the distal tip to the tapered portion and adding radiopaque material to the distal tip results in a combination of features which are not suggested by the references cited.

The Examiner's rejection of claims 17, 18, 20 and 22 under 35 U.S.C. Section 103(a) for being unpatentable over the Tovey patent in view of the Schroepfel

patent, as this rejection may be attempted to be applied to the amended claims, is respectfully traversed.

With respect to claim 17, it is noted that this claim as amended calls for the distal tip having a tip made of a temperature responsive hardness memory material modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder. Further, this claim calls for the tubular body being coated with a jacket made from the thermoresponsive hardness memory material. None of these features are disclosed in the references cited. In particular, note that Schroeppel is directed to a geometry memory sleeve and not to a temperature responsive hardness memory jacket which becomes soft and rubbery above a predetermined temperature.

Claims 12, 16 and 22 are directed to the braided wire addition to the catheter assembly defined in the claim from which each of these claims depend and are considered to be directed to a narrower patentable combination. Applicants acknowledge that this feature alone is known from the older Stevens U.S. Patent No. 3,485,234 and Alston Jr. et al, U.S. Patent No. 4,425,919.

Claim 21 brings out the feature of a tubular body of a catheter assembly being coated with a jacket of plastic thermoresponsive hardness memory material, which is harder at one temperature and softer at another temperature and which is modified or diluted with polyurethane resin to control the softening properties of the jacket. Accordingly, applicant submits that claim 21 is not taught by, suggested by, or obvious from the references cited by the Examiner, such as the Schroeppel patent which is directed to a geometry memory sleeve and not to a temperature responsive hardness memory jacket.

In summary, applicants submit that the catheter assembly defined in the

amended claims having a distal tip which is connected to a distal portion of a tubular body in a catheter assembly and which is made of a temperature responsive hardness memory material modified or diluted with polyurethane resin to control the softening properties of the thermoresponsive tip and compounded with a radiopaque material selected from one of barium sulfate, bismuth subcarbonate or a metal powder, which does not have a temperature responsive geometry or shape memory tip, and/or which has a jacket of thermoresponsive hardness memory material, is not at all disclosed or suggested by the references cited. Further, applicants submit that the combination of the feature of the memory hardness material, the modifying or diluting with polyurethane resin, the compounding with a radiopaque material, the tapering of the distal tip portion and the molding or welding of the distal tip to the distal portion define an unobvious and patentable combination not taught by or suggested by the references cited.

Applicants submit that an earnest endeavor has been made to place this application in condition for allowance and an early and favorably action to that end is requested.

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Respectfully submitted,


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